放影研
RERF

RADIATION EFFECTS RESEARCH FOUNDATION
財団法人 放射線影響研究所

ACT OF ENDOWMENT

Chapter I – General Provisions

(Name)
Article 1 – This juristic person shall be called "The Radiation Effects Research Foundation."

(Location of Office)
Article 2 – This juristic person shall have its principal office at 5-2, Hijiyama Park, Hiroshima City, Hiroshima Prefecture, and its subordinate office at 164 Sakurababa-cho, Nagasaki City, Nagasaki Prefecture.

Chapter II – Objectives and Activities

(Objectives)
Article 3 – The objectives of the juristic person shall be to conduct research and studies, for peaceful purposes, on the medical effects of radiation on man and on diseases which may be affected by radiation, with a view to contributing to the maintenance of the health and welfare of atomic bomb survivors and to the enhancement of the health of all mankind.

FOREWORD

On January 14, 1994, at the Moscow summit, the *Agreement Between the Government of the United States and the Government of the Russian Federation on Cooperation in Research on Radiation Effects for the Purpose of Minimizing the Consequences of Radioactive Contamination on Health and the Environment* was signed by Secretary of State Christopher and Foreign Minister Kozyrev. The purpose of this bilateral agreement is to support and facilitate joint cooperative research and exchange of information between the United States and the Russian Federation on the health and environmental effects of radiation.

The group established to implement this historic Agreement is referred to as the Joint Coordinating Committee for Radiation Effect Research (JCCRER). The first JCCRER meeting was held in Washington, October 24-25, 1994, and the following represents the record of this first meeting. Specific protocols and joint areas of research the two countries have agreed upon can be found in this publication which includes both the American and Russian versions of the text.

Done in Washington on 11/2/1994

United States Department of Energy
Office of International Health Studies
Washington, D.C. 20585

TABLE OF CONTENTS

Article 7 – The resources of the juristic person shall be maintained by the Chairman of the Board of Directors in a manner prescribed by the Board of Directors.
2. Permanent properties in the form of funds shall be deposited at a post office or a reliable bank, left in trust at the trust company, or maintained in the form of fully guaranteed valuable securities such as government and public bonds.

(Expenses)
Article 8 – Any expenses of the juristic person shall be paid from the operating properties.

(Plans of Activities and Budget)
Article 9 – The annual plans of activities and budget estimates of the juristic person shall be decided upon by the Board of Directors and thereafter submitted to the competent Minister(s) before the beginning of each fiscal year. The same procedure shall apply in case of changes in the plans of activities and budget estimates.

(Report of Activities and Settlement of Accounts)
Article 10 – The annual report of activities and settlement of accounts of the juristic person shall be submitted to the competent Minister(s) after review and audit by the Supervisors and approval by the Board of Directors, within three(3) months from the end of each fiscal year.
2. When the annual report is submitted to the competent Minister(s) in accordance with the provisions of the preceding paragraph, the inventory of assets as well as the balance sheet as of the end of the fiscal year shall accompany the report.

СОГЛАШЕНИЕ

между Правительством Российской Федерации и Правительством Соединенных Штатов Америки о

СОТРУДНИЧЕСТВЕ В ОБЛАСТИ ИЗУЧЕНИЯ РАДИАЦИОННЫХ ВОЗДЕЙСТВИЙ С ЦЕЛЬЮ МИНИМИЗАЦИИ ВЛИЯНИЯ ПОСЛЕДСТВИЙ РАДИОАКТИВНОГО ЗАГРЯЗНЕНИЯ НА ЗДОРОВЬЕ ЧЕЛОВЕКА И ОКРУЖАЮЩУЮ СРЕДУ

AGREEMENT

between the Government of the United States of America and the Government of the Russian Federation on

COOPERATION IN RESEARCH ON RADIATION EFFECTS FOR THE PURPOSE OF MINIMIZATION OF CONSEQUENCES OF RADIOACTIVE CONTAMINATION ON HEALTH AND THE ENVIRONMENT

Меморандум рабочего совещания

Объединенного Координационного Комитета по Изучению Радиационных Воздействий

Memorandum of Meeting

of the Joint Coordinating Committee on Radiation Effects Research

24-25 октября 1994 г.
г. Бетезда, штат Мэриланд

24-25 October, 1994
Bethesda, Maryland

as the Supervisors, and vice versa.

Article 14 – The Chairman and the Vice-Chairman to be elected in accordance with the provisions of paragraph 1 of the preceding Article shall be citizens of Japan or the United States of America, but the positions shall not be held by citizens of the same country at the same time. In principle, each of the positions shall alternate between the citizens of the two countries for every term of office.

2. The Permanent Directors to be elected in accordance with the provisions of paragraph 1 of the preceding Article shall consist of one citizen of Japan and one citizen of the United States of America.

3. The Directors to be elected in accordance with the provisions of paragraph 1 of the preceding Article shall consist of the same number of citizens of Japan and the United States of America respectively.

4. The Supervisors to be elected in accordance with the provisions of paragraph 1 of the preceding Article shall consist of one citizen of Japan and one citizen of the United States of America.

(Duties of Officers)

Article 15 – The Chairman shall represent the juristic person and manage the regular business thereof.

2. The Vice-Chairman shall assist the Chairman and, in the event that the Chairman is unable to perform his duties, shall perform all duties of the Chairman on his behalf.

3. The Permanent Directors shall assist the Chairman in administering the regular business of the juristic person.

4. The Directors shall participate in the decisions

- Dr. *Shlomo S. Yaniv* - Senior Technical Advisor, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission.

The Russian side was represented by:

Russian JCCRER members:

- Dr. *Vassily Iakovlevich Vozniak* - First Deputy Minister, Ministry of the Russian Federation for Civil Defense Affairs, Emergencies and Elimination of Consequences of Natural Disasters and Russian Co-chair;
- Dr. *Nikolai Nikolaevich Egorov* - Deputy Minister, Ministry of the Russian Federation for Atomic Energy;
- Dr. *Alexandr Dmitrievich Tsaregorodtsev* - Deputy Minister, Ministry of Health and the Medical Industry of the Russian Federation.

Russian EC members:

- Dr. *Leonid Alexandrovich Bolshov* - Director, Russian Academy of Sciences Nuclear Safety Institute and Co-Chair;
- Dr. *Lubov Ivanovna Anissimova* - Advisor to Minister, Ministry of the Russian Federation for Civil Defense Affairs, Emergencies and Elimination of the Consequences of Natural Disasters;
- Dr. *Mikhail Filippovich Kisselev* - Deputy Director, Federal Department, Ministry of Health and the Medical Industry of the Russian Federation;
- Dr. *Alexandr Pavlovich Panfilov* - Division Head, Ministry of the Russian Federation for Atomic Energy.

In accordance with the provisions of responsibility that were determined at the July 27-28, 1994 preparation meeting in Moscow, the American delegation reported on the proposed plan for implementation of activities under the Agreement. After discussion of the administrative and organizational structures to implement the program of cooperation the joint parties agreed to the adoption of the document with the following stipulations and instructions:

Within the framework of the Implementation Plan, it has been determined the parties to the Agreement may utilize different methods to fund and support both administrative and research activities under the Agreement. The Russian Federation intends to fund all activities through a centralized authority established by EMERCOM whereas the United States may utilize differing methods to support research institutions and researchers for activities jointly approved by both parties. The United States has not established the appropriate method to provide funding for administrative and operational costs that are necessary to oversee and administer the program of cooperation and are the responsibilities of both parties. The JCCRER by joint decision hereby instructs that within the next 60 days, the EC to the JCCRER will evaluate and report the following:

a) Determine the funding necessary to permit the development of proposals and feasibility studies for those research directions approved by the JCCRER for the

first year under the Agreement. Pending final agreement on financing research projects, both Parties have indicated that about 1 million dollars US and equivalent Russian assistance is available to support independent and cooperative aspects of research under the Agreement during the first year.

b) Evaluate and recommend the most appropriate method to ensure effective administration and oversight of operations under the JCCRER. At least two practical methods to be evaluated include the adoption of an Executive Secretariat that would be jointly supported by the parties or by utilization of an arrangement of joint support to be carried out by the Executive Agents to the Agreement.

c) Determine and propose the joint funding required by both parties to organize and support at least two workshops during the first year of the Agreement. At least one workshop should present the information and the data available from dose reconstruction and epidemiological studies that have already been performed in the U.S. and RF within the context of Directions 1 and 2.

d) Evaluate and propose the funding necessary and the methods for selection that would result in the selection of Scientific Review Group participants for the first and second scientific directions within the first year.

The Russian delegation reported on plans for research activities proposed under the program of cooperation. The parties upon review of the research activities proposed have agreed to the following:

1) For Direction 1, both parties agree to these research proposals with the stipulation that the EC should modify proposals 1.1 and 1.2 to 1) ensure data identification, quality assurance and preservation and to 2) accommodate the closer integration of the dosimetry (dose reconstruction) with the risk estimation for defined residential populations. Both parties agree that initial epidemiologic studies of residential populations should focus on, but not be limited to, stochastic effects in the South Urals populations.

2) For Direction 2, both parties jointly agree to adopt the program of research as presented with minor modification.

3) For Direction 3, the following conclusions were reached. The United States delegation proposed that no definitive decisions be made on project 3.2 until the U.S. has evaluated and coordinated on other potential inter-governmental Agreements that may more appropriately facilitate or support this area of research. With respect to 3.1 the JCCRER proposed that the EC be asked to evaluate this proposal and to further integrate these methodological research approaches with the activities defined in Direction 1 and Direction 2. The EC and the US should be prepared to report its conclusions to the

JCCRER within the next 60 days.

The American delegation presented the proposed guidelines for conducting joint scientific research under the Agreement. The parties endorse their adoption with the following stipulations:

The EC is instructed to further evaluate and report to the JCCRER on proposed modified language for incorporation within the guidelines to provide the following within 60 days:

1) Develop language that will ensure effective and efficient communication of research progress, interim and final results on a timely basis to the EC and JCCRER for release to the public.

2) Develop a mechanism to ensure the EC and JCCRER are advised and concur in the release of interim results and that such releases are fully coordinated in the Project Research Team. Measures should be included to ensure reasonable protection of scientific integrity and independence.

3) Propose language for inclusion in the guidelines to ensure strict adherence to intellectual property rights as prescribed in the Annex to the Agreement.

for the Russian Federation

Dr. Vassiliy Vozniak

for the United States of America

Dr. Tara O'Toole

IMPLEMENTATION PLAN

Proposed Implementation Plan under the Agreement Between the Governments of the United States of America and the Russian Federation on Cooperation in Research on Radiation Effects

1. BACKGROUND

The activities of nuclear industry, worldwide, during the last 50 years has resulted in significant contamination of the environment, and exposure to thousands of people among the general population and nuclear industry workers. Until recently much of the data related to these exposures remained classified. During the last few years a great deal of this information has been declassified, thus providing the opportunity to study the consequences of those exposures and greatly increase our understanding of the health effects of radiation.

The preservation, restoration and analysis of radiation exposure, medical, and environmental data is extremely important to the United States, the Russian Federation and to the world. These data may serve as the basis for new radiation effects studies that could offer conclusions that differ from those studies conducted in the past. Most of our knowledge on health effects and risks associated with radiation exposure is based on studies of persons exposed for medical purposes and studies of the atomic bomb survivors in Hiroshima and Nagasaki. The confounding factors in the studies on people exposed for medical reasons include an already diseased population, age and gender distributions which are unrepresentative of the general population, and in most cases, involve large doses, delivered at high rates, to just portions of the patients' bodies. The atomic bomb survivors were exposed to a very short burst of external radiation, which does not correspond to the pattern of exposure normally encountered or expected in the nuclear fuel cycle and in other uses of radiation and radioactive materials. In all radiation risk issues, there is no direct human database equal in robustness to that of the atomic bomb survivor database; and thus our current risk and regulatory policies are primarily driven by and extrapolated from the Hiroshima and Nagasaki data. However, the assessment of risk by extrapolation to low doses and dose rates, from data collected at high doses and rates, has not been validated and this issue is of premier importance for accurate risk assessment and management.

One of the world's most significantly contaminated areas is in the Southern Urals area of the Russian Federation. The Southern Urals databases may provide an opportunity to answer the question of whether chronic low-level exposures pose a coefficient of risk different from that previously assumed. The range of doses is comparable to Hiroshima-Nagasaki, and the exposed populations in the Russian Federation are larger. The significant differences are that the Southern Urals populations were chronically exposed over long periods of time, and the exposures

(2) Vice-Chairman
(3) Chief Researcher
(4) Head of the Secretariat
(5) Any Permanent Directors not included above and others to be designated by the Board of Directors from among the senior personnel of the Foundation.

3. The Operating Committee Members to be designated by the Board of Directors in accordance with item (5) of the preceding paragraph shall consist, in principle, of the same numbers of citizens of Japan and the United States of America.

4. The Operating Committee Members shall comprise the Operating Committee and shall consult on matters concerning the operation of the Laboratory and the Secretariat.

Chapter IX – Scientific Councillors

(Scientific Councillors)

Article 30 – This juristic person shall have not more than ten (10) Scientific Councillors.

2. The Scientific Councillors shall be selected and appointed by the Board of Directors, from among those who are possessed of expert knowledge and experience useful for carrying out the activities of the juristic person. The Scientific Councillors to be appointed shall consist of the same numbers of citizens of Japan and the United States of America respectively.

3. The Scientific Councillors shall constitute the Scientific Council, which reviews the scientific research programs of the juristic person, and makes recommendations to the Board of Directors with respect to

environment for the purpose of minimizing the consequences of radioactive contamination. Also noted in the Agreement, as a benefit to humanity, is the increased scientific understanding of the radiation effects upon the health and the environment.

4. STRUCTURE AND MEMBERSHIP

A. Joint Coordinating Committee for Radiation Effects Research (JCCRER)

Article III of the Agreement calls for the establishment of a Joint Coordinating Committee for Radiation Effects Research (JCCRER) to implement the Agreement. According to the Agreement, the JCCRER "shall consist of an equal number of representatives from each Party". It is proposed that, initially, four members be chosen by each Party to the Agreement. A Co-Chairperson for each Party shall be represented by a JCCRER member of each Executive Agent, which is responsible for coordinating the Agreement. The level of representation should be at the rank of Deputy Minister, Assistant Secretary, or equivalent, from key Ministries and Agencies involved in the cooperation within the framework of the Agreement. In the future, the membership of the JCCRER may be expanded upon mutual agreement of the Parties. It is initially proposed that the JCCRER meet annually, with meetings to be hosted by each Party on an alternate basis. Following is the proposed initial membership of the JCCRER:

United States of America:

U.S. Department of Energy
Tara J. O'Toole, M.D., M.P.H. (Co-Chairperson for United States of America)
Assistant Secretary for Environment, Safety and Health

U.S. Nuclear Regulatory Commission
E. Gail de Planque, Ph.D.
Commissioner

U.S. Department of Health and Human Services
Jo Ivey Boufford, M.D.
Principal Deputy Assistant Secretary for Health

U.S. Department of Defense
Joseph Osterman, Ph.D.
Director, Office of Environmental and Life Sciences

Russian Federation:

EMERCOM (Ministry of the Russian Federation for Civil Defense Affairs, Emergencies, and Elimination of Consequences of Natural Disasters)
Vassiliy Vozniak Sc.D., Prof. (Co-Chairperson for Russian Federation)
First Deputy Minister
Ministry of the Russian Federation for Atomic Energy
Nikolay Yegorov, Sc.C.
Deputy Minister
Ministry of Health and Medical Industry of the Russian Federation
Aleksandr Tsaregorodtsev, M.D., Prof.
Deputy Minister
To Be Named (either Russian Federation Ministry of Defense or State Committee on Sanitary and Epidemiological Surveillance of the Russian Federation)

Mission/Function of the JCCRER: Article III of the Agreement provides specific directions for the JCCRER as the main governing body under this Agreement. Article III.4 "The JCCRER will, within the framework of its jurisdiction, coordinate and review all aspects of cooperation under the Agreement and shall take such action as is appropriate for this Agreement's effective implementation." Article III.5 " The JCCRER may organize, establish and arrange working groups, conferences and seminars of specialists for joint discussion and study of specific topics related to the purposes of this Agreement. Specific projects and programs for radiation effects research, exchanges of scientific and technical safety information, personnel and equipment, and procedures for addressing and resolving questions of such matters as payment of costs under this cooperation, and patent and/or publications rights for joint activities administered under this Agreement may be developed separately by the JCCRER in accordance with the laws and regulations of the Parties." Article III.6 "The JCCRER shall generally establish on an annual basis, a program of cooperation to be implemented during the following year." Through review and approval of the program of cooperation, the JCCRER determines the overall research direction. The JCCRER defines the policy for conducting research within the framework of the Agreement by reviewing and approving guidelines for conducting research activities. The JCCRER receives direct administrative and technical support from the Executive Committee and scientific guidance and input from the Working Groups (as originally detailed in the joint Memorandum of Meeting of July 27, 1994, and hereafter referred to as Scientific Review Groups).

officers and other personnel;
(3) Inventory of assets;
(4) Record of assets and liabilities;
(5) Record of revenues and expenditures and supporting documents thereof;
(6) Documents concerning the minutes of the meetings of the Board of Directors and other meetings;
(7) Record of daily business;
(8) Documents to and from governmental and other public agencies; and
(9) Other necessary records and documents.

(Specific Rules for Operation)
Article 36 – Any other matters necessary for the execution of this Act of Endowment shall be separately established by the decisions made at the meetings of the Board of Directors

Supplementary Provisions

1. The initial Officers of this juristic person at the time of its establishment shall be as those listed in the attached sheet notwithstanding the provisions of paragraph 1 of Article 13.
2. The initial two (2) terms of office of the Chairman, the Vice-Chairman, and the Permanent Directors at the time of the establishment of this juristic person shall be three (3) years, notwithstanding the provisions of paragraph 1 of Article 16.
3. Notwithstanding the provisions of paragraph 1 of Article 31, the term of office shall be two (2) years

Affairs, Emergencies, and Elimination of Consequences of Natural Disasters)

Lyubov Ivanovna Anisimova, Sc.C. (designated rep.)
Advisor to Minister

Ministry of the Russian Federation for Atomic Energy

Alexandr Pavlovich Panfilov, Sc.C. (designated rep.)
Deputy Director of Federal Department

Ministry of Health and Medical Industry of the Russian Federation

Mikhail Filippovich Kiselev, Sc.C. (designated rep.)
Department Head

(other Russian Federation EC members identified by EMERCOM)

Mission/Function of the Executive Committee: The Executive Committee (EC) shall serve as a liaison between the JCCRER and the Scientific Review Groups. The EC will ensure direct communication between the partners within the Agreement, coordinate the work of national organizations, and ensure the effective and efficient implementation of the JCCRER's policies and program of cooperation. The EC shall: (1) be responsible for day-to-day communication between the partners for the coordination of JCCRER operations; (2) provide administrative and technical support to the JCCRER in developing the program of cooperation and drafting guidelines for conducting research activities under the agreement; (3) monitor and coordinate the activities of the Scientific Review Groups and Sub-Working Groups (as originally detailed in the joint Memorandum of Meeting of July 27, 1994, and hereafter referred to as Project Research Teams) and report progress to JCCRER members; (4) serve as liaison between Scientific Review Groups and JCCRER members, which includes the coordinating of Scientific Review Group activities and making recommendations to the JCCRER on the scope and nature of Scientific Review Group activities; (5) identify potential partner institutions and scientists in both countries; (6) organize and coordinate the annual JCCRER meetings.

C. Scientific Review Groups (SRGs) under the JCCRER

Co-Chairpersons and representation on each Scientific Review Group shall be appointed by each country's Executive Agent. Representatives should be prominent working scientists whose combined multidisciplinary expertise falls within the scope and nature of the Scientific Review Group activities. In addition, Scientific Review Groups representatives should not be directly involved in any projects under that Scientific Review Group. It is proposed that, initially, there be three Scientific Review Groups. Scientific Review

Groups may be added or discontinued by agreement of the members of the JCCRER. The following Scientific Review Groups are proposed:

Scientific Review Group 1 - Community Populations Health Effects Research (Main Emphasis on Stochastic Effects)

Scientific Review Group 2 - Worker Populations Health Effects Research (Main Emphasis on Deterministic Effects and Radiobiology)

Scientific Review Group 3 - Information Technologies and Decision-Making Support for Radiation Accidents and Health Effects from Radiation Exposure

Mission/Function of the Scientific Review Groups: The Scientific Review Groups shall serve the JCCRER in an advisory capacity. Within the scope of their research area, each Scientific Review Group shall be responsible for the scientific review and evaluation of the research carried out by the Project Research Teams, and shall make recommendations through the EC to the JCCRER regarding scientific research under the Agreement. The Scientific Review Group shall: (1) develop recommendations for research strategies, and support the joint development of research initiatives, concepts and proposals that are within the scope of the program of cooperation; (2) provide for scientific peer review and evaluation of project concepts and research protocols; (3) annually make recommendations to the JCCRER regarding the initiation, continuation, or completion of specific projects under the program of cooperation; (4) evaluate research progress of Project Research Teams; (5) report progress of research activities under the program of cooperation to the EC for transmittal to the JCCRER.

D. Project Research Teams (PRTs)

A Project Research Team shall consist of the team of principal scientists from both countries conducting the work on a specific project. A new Project Research Team shall be created for each project conducted under the program of cooperation. On completion of the project, the Project Research Team will be discontinued. The Co-Chairperson from each country shall be the designated principal investigators for that project.

Mission/Function: The Project Research Team shall develop and carry out the day-to-day research activities of a project conducted under the program of cooperation. The Project Research Team shall: (1) submit research proposals to the EC and Scientific Review Group(s); (2) conduct pilot

Chief of Research.

3. The Chief of Research shall supervise the scientific program of the Laboratory under the direction of the Chairman.

Moreover, the Japanese for *Chief of Research* will be amended from *Kenkyusho-no-shocho* to *Kenkyutanto-riji.*

RESEARCH GUIDELINES

Proposed Guidelines for Conducting Scientific Research Projects under the Agreement on Cooperation in Research on Radiation Effects

I. Background

All new cooperative research projects to be conducted under the Agreement on Cooperation in Research on Radiation Effects between the governments of the United States of America and the Russian Federation may be: (1) long-term studies, or (2) shorter term and limited in scope. All long-term projects will begin with a pilot phase effort to assess feasibility and will be followed by a full-scale long-term study if the pilot (feasibility) study is successful. Also, the long-term research effort must be judged mutually beneficial and cost-effective. A short-term project, limited in scope and not aimed toward a long-term research goal, may, with adequate justification be carried out under this Agreement without provisions for a pilot phase. These short-term limited scope studies will follow the guidelines described for pilot (feasibility) projects in Section II.

During the year following the first meeting of the Joint Coordinating Committee for Radiation Effects Research (JCCRER), the Executive Committee (EC) will facilitate the initiation of four or five initial pilot projects to assess the feasibility of eventual long-term projects. The EC will be responsible for selecting scientists in both countries to work in collaboration to develop the initial pilot projects. All first year pilot (feasibility) projects will focus on determining whether a potentially significant long-term study can be conducted and/or a comprehensive and suitable study protocol developed. The EC, with the agreement of the JCCRER, may also initiate a few limited-scope short-term projects during the first year. Any limited-scope project shall have a defined timetable as specified in the project plan. The merits of continuation of initial limited-scope projects will be evaluated by the JCCRER at the next annual meeting.

In subsequent years, new ideas (concepts) for research projects under the Agreement shall be brought to the attention of the JCCRER by the EC with the advice of the appropriate Scientific Review Group (SRG) at the annual meeting. After the first year, any new projects adopted by the JCCRER into the program of cooperation, shall be referred to the EC, who with the advice of the SRG, will identify scientific collaborators from both countries to form Project Research Teams (PRTs) to develop the project plan and carry out the research.

II. Pilot (feasibility) Projects

A. Development of Project Plan (proposal)

Plans for pilot (feasibility) projects shall be developed jointly by the PRT from the United States and the Russian Federation who are appointed to conduct the entire project. These plans should briefly describe the: background; specific aims; scientific rationale for conducting the project; research design and the procedures to be used to accomplish the specific aims of the project; tentative timetable for the project; specific tasks to be carried out by each side during the pilot project; resources needed to carry out the project; and collaborators from both sides. In addition, the pilot project plans should also describe how a determination will be made as to whether a full-scale project is appropriate and the type of longer-term research envisioned if the pilot project is successful. These pilot projects shall be limited in scope and have a specific end-point. The written project plan should be an abbreviated version of a full proposal for a long-term project described in Section III below. Plans for short-term or pilot projects involving contact with human subjects must be reviewed and approved by the appropriate institutional review boards in both countries. No pilot project shall last beyond the timetable specified in the pilot project plan, unless, after close scrutiny, the JCCRER determines that additional pilot work is deemed necessary before making a decision on launching a long-term project.

B. Acceptance Process

Proposals for pilot studies pursuant to long-term projects, or proposals for short-term cooperative projects, must be submitted through the Executive Committee to the appropriate Scientific Review Group (SRG) for review and evaluation. The SRG will review the proposals, evaluate the potential scientific merit of the project, and make recommendations to the EC. Each year the recommendations of the SRG shall be presented by the EC to the JCCRER at its annual meeting for acceptance.

During the year following the first meeting of the JCCRER, the EC will facilitate the initiation of four of five pilot projects that are most critical to the implementation of the highest priority long-term studies. Continuation of these projects shall be subject to review and acceptance by the JCCRER at the end of the first year. The EC may also initiate a few limited scope projects during the first year.

C. Reporting of Progress and Results

The PRT conducting the pilot study shall report progress to the Executive Committee Co-Chairs and the appropriate SRG Co-Chairs at least every four months. A final report which includes results, recommendations, and/or a protocol for future work should be submitted to the Executive Committee and the SRG on completion of the project. The EC will report on the SRG's recommendations and progress of all pilot studies to the JCCRER at their annual meeting.

III. Long-Term Projects

A. Development of Research Plan

Research plans shall be developed jointly by the PRT of scientists from the United States and the Russian Federation who are involved in the actual conduct of a project. The research plan should answer the following questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are your going to do the work? Each research plan should have the following sections:

1. **Abstract** - This should be a one-page summary of the specific aims, background and significance, and research design and methods.

2. **Specific Aims** - State the long-term objectives and describe what the specific research in this plan is intended to accomplish and the hypotheses to be tested.

3. **Background and Significance** - Discuss the background of the present plan, evaluate existing knowledge, present scientific rationale for conducting the study, and specifically identify the gaps which the project is intended to fill. State the importance of the research described in the plan and how it fits into the program of cooperation approved by the JCCRER.

4. **Preliminary Studies** - Discuss results of pilot or feasibility work that was conducted in preparation for the long-term project, and provide evidence that this plan is feasible.

5. **Research Design and Methods** - Describe the research design and the procedures to be used to accomplish the specific aims of the project.

Include the specific methods by which the data will be collected, analyzed, and interpreted. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Provide a tentative timetable for the investigation. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

6. **Quality Assurance/Quality Control** - Discuss specific procedures for ensuring the accuracy and quality of the data to be collected.

7. **Collaborators/Collaborating Institutions** - List the names and affiliations of collaborators for both countries, including one Principal Co-Investigator from each country. This is the team of principal scientists (PRT) conducting the work on the project. The specific roles of the collaborators in the conduct of the project should be clearly defined, along with a list of tasks to be conducted by the United States and the Russian Federation sides. Include a discussion of the existing resources to be made available for use by the study team.

8. **Human Subjects Considerations** - Describe the subjects who will be included in the investigation and how they will be enrolled. Identify the specific procedures, tests, and/or issues involving humans, and describe possible risks, ethical issues, and/or side effects for each. When the study involves contact with the subjects, describe in detail how informed consent will be obtained from study subjects. Describe in detail how privacy of individual study subjects will be protected. Questions to consider include, but are not limited to the following: (a) What is the subject being asked to do which he would not be doing if he were not part of this research project? (b) Does the research collect personally sensitive information? (c) How will confidential information collected for the study be protected?

9. **Itemized Budget (excluding personnel costs)** - List all supplies, equipment, and travel necessary to conduct the project and provide justification for each item requested. Personnel and overhead costs will be submitted separately by the PRT leader from each side to the funding agency(ies) in the respective country.

B. Peer Review and Acceptance of Research Plans

Research plans for all new long-term projects will receive scientific peer review. Research plans will be reviewed by the SRG first to assess

relevance to the overall goals of the cooperative program on late or other effects of radiation. Peer review will be provided or facilitated by the appropriate SRG and will focus on the scientific and technical merit of the proposal. Proposals that have already met the peer review requirements of the potential funding agency will not be subjected to further peer review. Projects involving human subjects must be reviewed and approved by the appropriate Institutional Review Boards in both countries. After approval by peer and Institutional Reviews, the proposals for feasibility or long-term studies will be submitted to the EC for referral to the JCCRER for final acceptance. For projects accepted into the program of cooperation, the EC will identify potential funding sources, and facilitate the funding process.

C. Conduct of Project

Each project shall be carried out by a PRT made up of scientists from the United States and the Russian Federation who are responsible for the day-to-day activities. Each project shall be conducted according to the terms of the protocol for the project. Minor changes in procedure will be worked out by mutual agreement between members of the PRT. Any major changes in scientific focus must be first submitted to the EC for referral to the JCCRER for approval. All changes are to be documented in progress reports to the Executive Committee and the appropriate SRG.

D. Reporting of Progress and Results

Each PRT shall provide written progress reports to the Executive Committee Co-Chairs and the appropriate SRG Co-Chairs at least every four months. These reports shall contain the following information: description of progress made during the four months, changes in procedures, equipment and supplies purchased, exchange trips taken, corrective actions taken as a result of quality assurance procedures, and milestones reached. All long-term projects shall be designed to produce information which is suitable for publication in the peer-reviewed scientific literature during the course of the project or on its completion. Manuscripts will be jointly prepared and submitted for publication by members of the PRT responsible for the project. In addition, each PRT shall develop and implement a public involvement plan designed to facilitate communication concerning the nature of the project and the project research results to the public at large. The EC will report SRG recommendations and PRT progress to the JCCRER at each annual meeting.

IV. Data Access and Sharing

During the conduct of any cooperative pilot, short-term, or long-term project, members of the PRT on both sides will have access to all data gathered for the project or to be used in analysis of results. After the PRT has had sufficient opportunity to prepare final reports, data used in the final analyses should be available to inquiring scientists. Procedures for allowing access to data collected for each pilot, short-term, and long-term project should be developed by the PRT and reviewed by the EC. Strict procedures should be applied to ensure that privacy of individual study subjects is protected. Existing public use databases might be used as a models or as vehicles for making these data available to the scientific community. A mechanism and timetable for data access and sharing should be developed, allowing reasonable time for the Project Research Team (PRT) to publish study results. In addition, an effort should be made to communicate the research results to the public at large.

V. Separately Funded Research Projects

It is recognized that some areas of potential mutual scientific interest exist where limited or small-scale studies could have the potential to contribute significant new scientific knowledge on radiation effects. These studies are not initiated or proposed to necessarily conform to the JCCRER process applicable to other short-term studies. These studies should be fully coordinated with the JCCRER activities to avoid unnecessary duplication of efforts. Recognition of the cooperative relationship between separately funded research and that performed under the JCCRER cooperative research program is essential to a fully successful research program.

Projects of any size and duration, which pre-date the signature of the Agreement and are separately funded by participating agencies should also be fully coordinated with the EC during the year following the first JCCRER meeting.

Both pre-existing and new projects that are separately funded research projects may be offered for consideration and joint funding under the JCCRER cooperative research program at the sponsoring agency's option. In such cases, submitted studies should demonstrate conformity to the JCCRER review guidelines as outlined in the above Sections, prior to adoption by the JCCRER.

PROPOSALS

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COOPERATION IN RESEARCH ON
RADIATION EFFECTS FOR THE
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CONSEQUENCES OF RADIOACTIVE
CONTAMINATION ON HEALTH
AND THE ENVIRONMENT

Direction 1

MEDICAL ASPECTS OF RADIATION EXPOSURE EFFECTS ON POPULATION

PROJECT 1.1

Dose Reconstruction for the Population Subjected to Radiation

Moscow
1994

PROJECT 1.1

Dose Reconstruction for the Population Subjected to Radiation

1 Background

Technological dumps of the radioactive materials into the atmosphere. waste dumps into Techa river, occurred in 1949–1956, emergency situations in 1957 and 1961 resulted in high exposure levels of the population in the region of the river Techa and the Eastern Ural radioactive trace. The information on the radioactive contamination of the environment, source characteristics, and dosimetry studies requires systematization and estimation.

Since 1986 large scale dosimetric studies of the population subjected to radiation after the Chernobyl accident are performed.

The aim of the project is the improving of the reconstruction methods of the internal and external population exposure dozes, and the doze reconstruction itself for the population with the maximum exposure rate.

2 Directions of work

Analysis and systematization of all archive information on Ural district including:

- measurements of the radioactivity in the environment objects, which started from 1951;
- personalized data on migration for 90,000 people — residents of the most contaminated territories;
- life–time measurements of the radionuclide content of the whole bogy (12 thousand persons), separate organs (15 thousand persons), autopsy data (since 1951).

System analysis of the archiv information on regions contaminated by radionuclides after the Chernobyl accident includes:

- measurements of radioactivity in the environment, which started from 1986;
- dosimetric data on external and internal irradiation.

Continuation of the dosimetry investigations using whole body counting, electron spin resonance, thermo–luminiscent dosimetry methods.

Development of the data reconstruction models of the external (under conditions of the radioactive contamination of the local site and the atmosphere) and internal exposure from long–living plutonium, strontium–90, cesium–137, tritium, short–living iodine–131, and other radionuclides with account for the local conditions.

Improving of the databases and software for the exposure doze reconstruction.

Reconstruction of the personal exposure dozes and estimate of the reliability of the obtained data.

3 First–year works of the project

- proofing of the project;
- detailed formulation of the aims and tasks of the project;
- choice of partners;
- collecting and preliminary estimate of the accumulated data on the radioactive contamination of the environment and results of the dosimetry measurements;
- determination of the sources and amount of funding;
- detailed planning of the joint work.

4 Assumed Russian participants of the project

- Ural Research Center for Radiation Medicine;
- St.Petersburg Radiation Hygiene Institute;
- The First Branch of the Biophysics Institute of the Russian Ministry of Health;
- Industrial Association "MAYAK".

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Direction 1

MEDICAL ASPECTS OF RADIATION EXPOSURE EFFECTS ON POPULATION

PROJECT 1.2

Risk Estimation for the Deterministic and Stochastic Exposure Effects and the Results of Actual Observations of the Population Health in the Region of the Industrial Association "MAYAK"

Moscow
1994

PROJECT 1.2

Risk Estimation for the Deterministic and Stochastic Exposure Effects and the Results of Actual Observations of the Population Health in the Region of the Industrial Association"MAYAK"

1 Background

Sufficiently high population exposure levels in the region of Techa river and the Eastern Ural radioactive trace, which would be determined more accurately in the framework of the project "Reconstruction of the internal and external exposure dozes for the population of the Ural region", allow the estimate the possible deterministic and stochastic effects with the use of the already existing models and those under development. Long demographic, epidemiologic, and direct clinical observations of the health of the exposed population and specially chosen control groups were performed in the region. More than 40–year time period after the start of the exposure seems to be long enough to obtain the reliable estimates of the possible harmful impact of the radiation on the human health.

The aim of the project is the comparison of the risk estimates for the deterministic and stochastic effects of radiation with the results of actual health observations of the residents of the "MAYAK" site.

2 Directions of work

Analysis, systematization, and estimate of the archive information on demographic, epidemiologic, and direct clinical observations of the health of the exposed population and specially chosen control groups.

Development of the models, estimating the radiation risk, with account for the demographic (including ethnic) specific features of the exposed population.

Formation of the risk groups according to the estimated doses of the external and internal exposure of the population.

Estimate of the possible deterministic and stochastic effects with account for various models and ambiguities in the data on the exposure dozes and in the risk coefficients for the appearance of the oncologic diseases and death rates from cancer of various localization.

Comparison of the results of the risk estimates with the actual observation data in time dynamics after the start of the human exposure.

3 First–year works of the project

- proofing of the project;
- detailed formulation of the aims and tasks of the project;
- choice of partners;

- collecting and preliminary estimate of the accumulated observation data on the population health;
- determination of the sources and amount of funding;
- detailed planning of the joint work.

4 Assumed Russian participants of the project

- Ural Research Center for Radiation Medicine;
- Experimental Research Station of the Industrial Association "MAYAK";
- Biophysics Institute of the Russian Ministry of Health;
- Nuclear Safety Institute of the Russian Academy of Sciences (IBRAE).

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Direction 2

RESEARCHES ON MEDICAL CONSEQUENCES OF PERSONNEL EXPOSURE TO RADIATION

PROJECT 2.1

Metabolism and Dosimetry of Plutonium Industrial Compounds

Moscow
1994

Metabolism and Dosimetry of Plutonium Industrial Compounds

1 Background

The experience of rehearsers in the field of radiation safety shows that the main factor of professional health hazard is still incorporation of high–toxic radionuclides of plutonium and in less extend of americium.

The aim of the research project is to improve the efficiency of the methods for transuranium radionuclide dosimetry using the information collected by Russian and American scientists on metabolism of these substances in human organism.

The subject of collaboration is unification of approaches to estimation of accumulated radionuclide products in human organism, modification of bio–kinetic models of plutonium penetration for reconstruction of exposure doses for organs and tissues from the data on radionuclide excretion with urine and feces.

The researches are based on the data from Dosimetry Register of MAYAK Industrial Association (americium 241 in organs and tissues, more than 750 cases) and from Transuranium Register of the United States (more than 350 cases).

As a part of the research program, participants intend to compare the data of different radiochemical analysis of plutonium 239, 240, and americium 241 in biosubstrates; to standardize procedures; to elaborate general rules for keeping records in dosimetry section of the Register.

The joint researches will be completed with the development new procedure "Analysis of incorporated plutonium dozes received by organs and tissues of the personnel subjected to inhalation of this radionuclide", which will include the latest advances in metabolism.

2 Directions of work

The first stage of the work will be devoted to the comparative analysis of data (received from autopsy material analysis) on distribution of plutonium 239, 240, and americium 241 in organism, and of the sampling methods and radio–chemical procedures for detection of radionuclides in biosubstrates. Russian and American data will be used for reconstruction of the model of plutonium excretion with urine, long afterwards receiving of radionuclide by an organism. The effect of pathologic processes on the plutonium distribution and excretion will be also examined.

The model of lung clearance for different plutonium compounds will be compared with ICRP publ. 64 model (with account of procedure for aerosol classifying by solubility, used in Russia). As a consequence, a common approach will be developed for estimation of lung exposure by nuclide excretion long afterwards the inhalation.

Generalizing the common data on kinetics of plutonium redistribution between organs, researchers will refine the estimation of effective dose due to incorporated plutonium.

The final stage will be completed by the comparative analysis of plutonium metabolism of personnel and population, who had no professional contact with radionuclides. As a result of the work, a handbook for estimation of personnel exposure will be issued.

3 First year works of the project

- Discussion and feasibility study of the project, elaboration of objectives and tasks for the first and the following stages of co–operated researches.
- Selection of a Laboratory in the United States and partners for the research.
- Estimation of the total volume of work and determination of financial sources from Russia and the United States.
- Comparative analysis of the generalized data on radionuclide distribution (plutonium–239, –240 and americium–241) in bodies of the departed specialists (the data obtained in the United States, Russia, and other countries).

4 Assumed Russian participants of the project

- The First Branch of the Biophysics Institute of the Russian Ministry of Health;
- Industrial Association "MAYAK".

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Direction 2

RESEARCHES ON MEDICAL CONSEQUENCES OF PERSONNEL EXPOSURE TO RADIATION

PROJECT 2.2

Risk estimation for deterministic and stochastic (carcinogenic) sequences of occupational exposure

Moscow
1994

PROJECT 2.2

Risk estimation for deterministic and stochastic (carcinogenic) sequences of occupational exposure

1 Background

Factors of radiation risk form the basis of the Safety Radiation Standard. At present, the radiation risk is estimated in details for persons irradiated in result of the nuclear explosion in Japan.

Nowadays, there is a vital need to refine factors of deterministic and stochastic risk of prolonged exposure, which affected personnel of nuclear plants and population of the contaminated territories.

In the United States and Russia, Registers are developed for personnel, who were working in military nuclear plants during the period of their commission. In result of hard working-conditions (especially in Russian plants), large part of the staff was overirradiated. For example, of 20,000 personnel of the Industrial Association "MAYAK" included in Russian Register, more than 50% obtained doses of external gamma-radiation exceeding maximum permissible ones.

Integration of dosimetry and medical data from the Russian and American Registers will give reliable estimates for deterministic and carcinogenic risk for chronic occupational exposure (external gamma-radiation and internal alpha-radiation) in wide range of doses. Then the results may be compared with the known risk factors, obtained in Japanese cohorts.

2 Directions

Main lines of the research are as follows:

- Coordination of methods for epidemiological study;
- Selection and verification of radiation-risk models for deterministic and carcinogenic sequences of occupational exposure;
- Refining of the accumulated doses of external and internal exposure of "MAYAK" personnel in terms of modern knowledge of metabolism, dosimetry and radiobiology, including those received in the framework of the Project, section 2-1;
- Epidemiological study of deterministic and carcinogenic risk of prolonged occupational exposure to external gamma-radiation and internal alpha-radiation.

At the first stage, methods and volume of work are to be co-ordinated.

3 First-year works of the project

Feasibility study of the long-term program of the co-operated researches, revision of the objectives and tasks, selection of partners, estimation of volume of work and determination of financial sources, revision of calendar plan for the following stages of work.

In addition, the Russian Party proposes a pilot project on non–stochastic risk by the example of plutonium pneumosclerosis, which is included in the Russian Register for personnel of plutonium–production plants.

4 Assumed Russian participants of the project

- The First Branch of the Biophysics Institute of the Russian Ministry of Health;
- Industrial Association "MAYAK".

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CONTAMINATION ON HEALTH
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Direction 3

INFORMATION TECHNOLOGIES IN RESEARCHES ON RADIATION EFFECTS AND DECISION–MAKING SUPPORT

PROJECT 3.1

Development of the Methodology of the Data Analysis for the Estimation and the Prediction of the Radioecological Situation, for the Risk Estimation of the Population under Accident Conditions, and for Decision–Making Support for the Population Protection in Possible Radiation Accidents

Moscow

1994

Development of the Methodology of the Data Analysis for the Estimation and the Prediction of the Radioecological Situation, for the Risk Estimation of the Population under Accident Conditions, and for Decision–Making Support for the Population Protection in Possible Radiation Accidents

1 Background

The experience of work on elimination of the effects of the Chernobyl accident, South Ural accident and other severe radiation accidents in Great Britain and USA has shown that the problem of optimization of the decision–making processes on population protection and territory rehabilitation is difficult and has multiple factors. The crucial element of making decisions in extreme situations is, in most cases, the absence of the system informational support and on–line analysis and scientific expertise of the whole complex of the available information. As a result, in actual situations some simple conservative estimates are used, which are based on statistical models for the calculation of the population exposure doses through "critical paths and critical factors" of the radiation impact (the principle of "human protection").

At the moment it seems to be premature to put on the problem of designing of the integral computer systems, which would provide the total support of the decision–making process in the actual time scale. However, several problems, in particular, designing of models, using actual data bases, can already be solved in the form of computer codes, applicable in the decision–making process.

2 Directions of work

The designing of the supporting systems for decision making at radiation accidents should account for the following:

- the necessity to work with both the primary information, which characterizes the evolution of the radiation situation and general situation in the region of contamination, and with the secondary information, which interprets situation using simple or complicated models;
- the necessity to account for the large amount of diversified data with different levels of reliability and sources of uncertainty, various and often complicated statistical distributions, and significant dispersions;
- the necessity to account for the result of the analysis of sensitivity and uncertainties in the predicted exposure doses and risks, both for the critical groups and for the whole population under exposure;
- the necessity to make the spatial analysis of the large number of radiation, ecological, medico–demographic, social–economical, and other parameters, which characterize the evolution of the situation in the contamination zone;

- the necessity to account for the conflict between the "threshold" values of the regulating norms and broad distribution functions of the actual parameters under control.

On the first stage it seems to be reasonable to work in the following directions:

- development of the bank of the required models (estimation of the radiation situation, dispersion of radionuclides in various members of the ecological chains, calculation of the population exposure doses, risk estimates, etc.) and methods for the sensitivity analysis;
- analysis of model sensitivity to the uncertainties of the input data, model parameters, and peculiarities of their distribution functions;
- elaboration of the requirements to the ccompleteness and reliability of the database information, according to the model demands;
- elaboration of the possible scenarios of making decisions on the basis of the model results.

3 The first–year works of the project

- proofing of the project;
- detailed formulation of aims and tasks of the project;
- choice of partners;
- determination of the source and amount of funding;
- planning of joint works.

4 The assumed Russian participants of the project

- Nuclear Safety Institute of the Russian Academy of Sciences (IBRAE);
- St.Petersburg Radiation Hygiene Institute;
- Insitute of Agricultural Radiology and Agroecology;
- Ural Research Center for Radiation Medicine;
- Biophysics Institute of the Russian Ministry of Health.

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CONTAMINATION ON HEALTH
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Direction 3

INFORMATION TECHNOLOGIES IN RESEARCHES ON RADIATION EFFECTS AND DECISION–MAKING SUPPORT

PROJECT 3.2

Using of the results of joint researches in decision making–support systems of regional crisis centers

Moscow
1994

PROJECT 3.2

Using of the results of joint researches in decision making–support systems of regional crisis centers

1 Background

Project 3.1 makes provisions for integration of the experience obtained in modern computer systems and technologies for decision-making support. Other joint projects (1.1, 1.2, 2.1, 2.2) make provisions for obtaining of a large amount of estimated data, methods, and recommendations, which can be used by district administrations in practical activities on elimination of the effects of the happened accidents and possible crisis situations.

In 1992-94, in the framework of the particular agreements, Nuclear Safety Institute of Russian Academy of Science, in co–operation with Industrial Association "MAYAK" and All-Russian Scientific Research Institute of Theoretical Physics, created prototypes for divisions of the Technical Crisis Center (TCC) of the Emergency Committee of Chelyabinsk Regional Administration, including: a system for representing of radiation–monitoring data, models for prediction of radionuclide environmental spreading, specializes regional geo–informational system, system for decision–making support in case of radiation accidents (with "MAYAK" taken as an example).

So, there is ground for a practical application of the results of the co–operative works on rehabilitation of suffered population and specialists, and making provisions for their effective usage in crisis situation.

The objectives of the Project are creation and commission of a subsystem of Regional Technical Crisis Center for supporting decisions on the population protection in case of radiation accidents for the Ural district.

Within the framework of the project the conditions for the efficiency analysis of the developed systems will be provided.

2 Directions of work

To solve this problem within 2.5–3 years, using the available system for support of Region Administration's decisions, the following work is to be done:

1. Provision of the TCC with additional equipment , including up–to–date communication lines between the Crisis Center of the Chelyabinsk Administration, MAYAK Industrial and Scientific Association, and EMERCOM (Russian Federation) to assure the effective exchange of information.

2. Creation of a fragment of the radiation monitoring system on the basis of dose rate sensors in the neighborhood of Chelyabinsk, integration of radiation monitoring data into a system of primary processing and cartographic representation of information.

3. Creation of the information systems based on the results of the projects, realized in the framework of the Agreement, and including them in the decision–making–support system.

4. Development of the model banks, software of the specialized geo–information system, integrated systems for decision–making support as applied to regional conditions and possible emergency situations, including:

   (a) Improvement of the typical system for modelling of radionuclide spreading in atmosphere, including local and intermediate–scale models.

   (b) Improvement of the typical system for modelling of radionuclide spreading in water media.

   (c) Development of the code module for correction of the radiation monitoring prediction on the basis of actual radiation–monitoring data.

5. Organization of the training service in the TCC for regular subject training (businesses games) with high reliability of simulation of various possible situations, using computer codes and geo–information system. Businesses games are intended for training specialists of the TCC, officials of federal and industrial structures, and regional administration of different levels for activity in crucial situations.

3 First year works of the project

- Feasibility study of the Project;
- Elaboration of objectives and tasks of the Project;
- Selection of the partners for the research;
- Estimation of the total volume of work and determination of financial sources;
- Specification of the plan for the co–operative works.

4 Assumed Russian participants of the project

- Emergency Committee of Chelyabinsk Regional Administration;
- Nuclear Safety Institute of the Russian Academy of Sciences;
- Industrial Association "MAYAK".

СОДЕРЖАНИЕ